Pride Mobility Products Corp.

Research & Development
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West Pittston, PA 18643
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OCT 6 – 2004

Exhibit 1

K092612

510(k) Summary
Pride Mobility Products Corporation
Jazzy 600 Power Wheelchair

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Thomas Schappert
Official Correspondent

Date Prepared:
09-10-04

Name of Device and Proprietary Name:
Jazzy 600 / Pride Mobility

Common or Usual Name:
Powered Wheelchair Base Unit

Classification Name:
Physical Medicine / Wheelchair, Powered

Product Code:
ITI

Comparison to Predicate Devices:
The Jazzy 600 is substantially equivalent to the Pride Mobility Jazzy (K945936) when comparing performance, maneuverability, stability, dimensions, and geometry. The performance characteristics and the position of the drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. Both utilize our patented Mid-Wheel Drive technology, rear casters, and front anti-tip devices for added stability and maneuverability. Key changes between the Jazzy (K945936) and the Jazzy 600 are the replacement of the front anti-tip wheels with front anti-tip casters that have nylon spheres that resist wheel hang-ups. The Jazzy 600 also has side mounted, users accessible freewheel release levers, and front battery access.

Device Description:
The Jazzy 600 is a battery-operated power wheelchair featuring Mid-Wheel Drive technology, rear casters, front anti-tip casters, and a standard 75 amp Pride Flight controller. The Jazzy 600 is designed for, but not limited to Pride Mobility Products Corp. providers / retailers and their consumers.

The Jazzy 600 Power Wheelchair consists of the same basic components found on the Jazzy (K945936), such as a rigid steel frame, upholstered seat, armrests, footplate, drive wheels, rear caster wheels and front anti-tip devices. As a motorized wheelchair substantially equivalent to the Jazzy (K945936) it also offers 2 motors for operational purposes, electronic regenerative disc brakes, suspension, onboard battery charger, a fully programmable controller, and requires two batteries. Accessories include lap belt, rear basket, cane or crutch holder, oxygen holder, walker holder, flag holder, cup holder, saddle bag, and dust cover.

The Jazzy 600 is designed with ultimate safety, stability, and performance in mind. It features rear casters, and front anti-tip casters which allow for surface contact at all times and prevents pitching on sloped terrain.

Intended Use:
The intended use of the Pride Mobility Products Corp. Jazzy 600 Power Wheelchair is to provide mobility to persons limited to a seated position, that have the capability of operating a powered wheelchair.

Non-Clinical Testing:
Compliance to applicable Testing Standards is as follows:
ANSI/RESNA WC/01 Determination of Static Stability
ANSI/RESNA WC/02 Determination of Dynamic Stability
ANSI/RESNA WC/03 Effectiveness of Brakes
ANSI/RESNA WC/05 Overall Dimensions, Mass & Turning Space
ANSI/RESNA WC/08 Test methods for Static, Impact and Fatigue Strengths
ANSI/RESNA WC/09 Climatic Tests
ANSI/RESNA WC/10 Obstacle Climbing
ANSI/RESNA WC/15 Documentation and Labeling
ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.
ANSI/RESNA WC/93 Maximum overall Dimensions
CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The Jazzy 600 has the same intended use and similar technological characteristics as the Jazzy (K945936), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Jazzy 600 is substantially equivalent to the predicate device (Jazzy). The Jazzy 600 has passed all the necessary testing procedures and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 - 2004

Mr. Thomas Schappert
Official Correspondent
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

Re: K042612
Trade/Device Name: Jazzy 600 Powered Wheelchair
Regulation Number: 21 CFR 890. 3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 30, 2004
Received: October 1, 2004

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: Jazzy 600 Powered Wheelchair

Indications for Use:

The intended use of the Pride Mobility Products Corp. Jazzy 600 Powered Wheelchair is to provide mobility to persons limited to a seated position.

Prescription Use ___X___ **AND / OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042612